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11. 510(k) Summary K052188

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Company Name: Rhythmlink International, LLC
917 Brookwood Drive
Columbia, South Carolina 29201

Phone: (803) 252-1222
FDA Registration #: 1067162

Official Contact Person: James M. Mewborne
Engineering & Regulatory Manager

Summary Date: October 22, 2004

Device Identification: Proprietary Device Name:
Rhythmlink International Cutaneous Pad Electrodes

Generic Device Name: Cutaneous Electrodes

Regulatory Class: Class II
Classification Name: 21 CFR 882.1320,
Cutaneous Electrode

This device has not been previously submitted to the FDA.

Predicate Device(s): **Bio-logic Systems Corp**
510(k)#: K941799

Device Description:
Rhythmlink International Cutaneous Disposable Electrodes are single patient use, disposable devices. Electrodes are non-invasive as they are applied to the patient's skin using a self-adhesive solid-gel surface. The electrodes consist of a cotton non-woven pad with a Silver/Silver Chloride carbon layer and a solid Hydro-gel adhesive layer. The electrodes are attached to a lead wire and terminate at the opposite end using a DIN 42-802 type safety connectors.

Intended Use:
The Rhythmlink International Cutaneous Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of stimulating /recording of biopotential signals. Electrodes are applied in the study of biopotentials such as Electroencephalograph (EEG), surface Electromyography (EMG), nerve conduction Evoked potential signals (EP). Electrodes are non-

invasive as they are applied to the patient's skin using a self-adhesive solid-gel surface. The electrodes are non-sterile and for single patient use only.

Technological Characteristics:

The electrodes consist of a lead wire terminating on a carbon fiber pad. This pad is made up of three primary layers. A cotton nonwoven micro pore fabric, a carbon fiber layer for greater electrical characteristic and a Hydrogel used to temporarily adhere to the patient's skin. The lead wire is terminated on the opposite end using a safety connector DIN 42802 which is subsequently used to interface with the monitoring device. This connector does not allow connection to an A/C outlet. The characteristics of the Rhythmlink International Cutaneous Electrodes are substantially equivalent to the predicate devices already being legally marketed in the United States. The performance is expected to be the same as the predicate device. No new questions of performance, safety or effectiveness are raised.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2005

Rhythmlink International, LLC
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K052188
Trade/Device Name: RLI Cutaneous Disposable Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: August 10, 2005
Received: August 11, 2005

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Buchman
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8. Indications for Use

510(k) Number (if known): K052188

Device Name: RLI Cutaneous Disposable Electrode

Indications for Use: The Rhythmlink International Cutaneous Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of stimulating /recording of biopotential signals. Electrodes are applied in the study of biopotentials such as Electroencephalograph (EEG), surface Electromyography (EMG), nerve conduction Evoked potential signals (EP). Electrodes are non-invasive as they are applied to the patient's skin using a self-adhesive solid-gel surface. The electrodes are non-sterile and for single patient use only. These devices are restricted to sale by or on the order of a practitioner licensed by the Law of the State in which he/she practices.

Prescription Use ___X__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Burlund MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052188